Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

27-Oct-00

Aquarius Medical Corporation, Inc.
16047 North 82nd Street
Scottsdale, Arizona 85260

Tel - (480) 991-1818

Fax - (480) 991-4335

Official Contact:	Michael McCauley, President
Proprietary or Trade Name:	AcroTherm
Common/Usual Name:	AcroTherm
Classification Name:	Thermal Regulating System
Device:	AcroTherm
Predicate Devices:	Aquarius Medical Corporation, Inc. Thermo-STAT - K970367 MTRE Advanced Technology, Inc. Allon 2001 - K001546

Device Description:

The Aquarius Medical Corporation's AcroTherm consists of the following elements:

- Warming chamber with tubing set
- Control Unit
- Tubing Set
- Disposable Arm Liner

The AcroTherm is a compact, portable thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand and forearm.) The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand & forearm), which should not impede standard patient care and/or full body access.

Indicated Use:

The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

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Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The AcroTherm is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

		Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	**AQUARIUS MEDICAL CORPORATION**	**MTRE**
Product	**AcroTherm**	**Thermo-Stat K970367**	**Allon 2001 K001546**
Intended Use	Patient Temp. Control Hypothermia	Patient Temp. Control Hypothermia	Patient Temp.Control Hypo/hyperthermia
Intended Population	Adult patients	Adult patients	Adult *and* pediatric patients
Prescription Device Only	Yes	Yes	Yes
Use Environment	Hospitals and healthcare facilities	Hospital	Hospital
Design Features			
Type	Neg Pressure/ Water Perf Pad	Neg Pressure/ Therm Pad	Hot Water Perfusion Pad
Pressure Device	Yes-neg	Yes-neg	No
Sub-atmospheric pressure (mmHg)	40±5	40-60	NA
Electric (AC)	Yes	No	Yes
Temp. Range	≤45 °C	≤45°C	≤40.2°C
Application Site	Distal Limb	Distal Limb	Up to Whole Body
Disposable Type	Limb Cover	Thermal Pad/Seal	Perfusion Pad
Control System			
Controller Type	Micro-logic	NA	Micro-Processor
Size	14x6x5in	NA	103x21x20in
Weight	<5lb	NA	73lb

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Product	**AcroTherm**	**Thermo-Stat K970367**	**Allon 2001 K001546**
Mobility	Hand-held	NA	4 wheels
Water Tank	450 – 500 ml	NA	6 Liter
Flow Rate	< 500 ml/min	NA	.2-1.25L/min
Safety			
High Temp Alarm	Yes	No	Yes
Water Level	Yes	NA	Yes
Chamber Sub-atmospheric pressure	Yes	Light	NA
Seal Pressure	Yes	Light	NA
Materials			
Chamber	ABS	Polycarbonate	NA
Heating Pad	Urethane	PVC	
Disposable	Urethane	PVC	
Contraindications	Patients under 18. Patients with peripheral vascular disease.	Patients under 18. Patients with peripheral vascular disease	Patients with open, widespread skin lesions that will contact the device or patients with multiple trauma

Differences between Other Legally Marketed Predicate Devices:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Aquarius Medical Corporation
c/o Mr. Mike McCauley
President
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

Re: K003368
Trade Name: AcroTherm™
Regulatory Class: II (two)
Product Code: DWJ
Dated: January 2, 2001
Received: January 4, 2001

Dear Mr. McCauley:

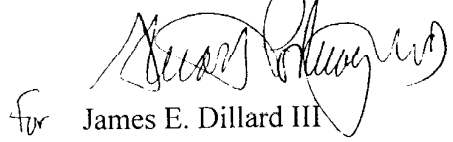
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-5648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K003368 (~~To be assigned~~)

Device Name: AcroTherm

Intended Use: The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K003368

1-18-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003368

Prescripton Use ✓ **or** **Over-the-Counter Use**_____
(Per CFR 801.109)